DEC 2 0 2005

5 510(k) Summary

K052467 – Kyron™ Clinical Imaging BrainViewRx™ Viewer

1. Contact Information

Submitter
Kyron Clinical Imaging, Inc.
2433 N. Mayfair Rd., Suite 103
Wauwatosa, WI 53226

Contact Person
Michael Schmainda, CEO
Phone 414-727-1930
Fax 414-727-1939

Date Summary Prepared: November 10, 2005

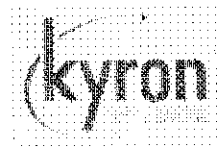
2. Device Name and Classification

The proprietary name of the device to be introduced into interstate commerce is the BrainViewRx software package. It is image processing software running on a personal computer platform, and is classified under regulatory product code 90 LLZ (regulation # 892.2050), "Picture archiving and communications systems" as a class II medical device.

3. Identification of Legally Marketed Equivalent Predicate Devices

Predicate System	*Manufacturer*	*Reg. Data*
Fusion 7D Multi-modality registration workstation software	Mirada Solutions Ltd. Oxford Centre for Innov. Mill Street, Oxford OX2 OJX United Kingdom	K020546 SE 10/11/2002 Product code LLZ Class II
Eloquence Integrated Functional Imaging System	MRI Devices Corp. 1515 Paramount Dr. Waukesha, WI 53186	K023130 SE 10/11/2002 Product code LNH Class II
Syngo® Multimodality Workstation	Siemens Medical Systems 186 Wood Ave. South Iselin, NJ 08830	K010938 SE 6/26/2001 Product code LLZ Class II

K052467



4. Description of Device

BrainViewRx is an image processing software package for the visualization and manipulation of clinical imagery of multiple kinds. It brings sets of anatomical, physiologic and/or functional imagery into alignment and provides a variety of display and analysis options for utilizing the imagery relationships.

5. Statement of Intended Use

BrainViewRx™ provides visualization of functional and physiologic brain imaging data. The software package provides both analysis and viewing capabilities that promote the integration of physiologic and functional imaging data sets, including blood oxygen level dependent (BOLD) fMRI and magnetic resonance spectroscopy (MRS). The integration of these data, when interpreted by a trained physician, yields information that may assist in the diagnosis of brain pathology and the planning and monitoring of medical treatments.

6. Predicate Device Comparison of Technological Characteristics

The BrainViewRx Viewer image display capabilities are substantially equivalent to the Mirada Solutions Fusion 7D software package, and the image processing software provided with the MRI Devices Eloquence workstation. The selection of imagery displayed by BrainViewRx is substantially equivalent to Siemens *syngo* software. BrainViewRx provides similar capabilities for processing and integrated display of clinical imagery from a variety of sources.

7. Performance Study

FDA has not established special controls or performance standards for this device. Software verification and validation was conducted to confirm proper function of the device's features.

8. Safety information

No new safety hazards are introduced by the use of the BrainViewRx software package in comparison to the software of the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 17 2006

James L. Reuss, Ph.D.
Chief Technology Officer
Kyron Clinical Imaging, Inc.
2457 N. Mayfair Rd., Suite 202
WAUWATOSA WI 53226

Re: K052467
Trade/Device Name: BrainViewRx™ Viewer
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: April 24, 2006
Received: April 28, 2006

Dear Dr. Reuss:

This letter corrects our substantially equivalent letter of December 20, 2005.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to continue marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

4 Indications For Use

510(k) Number (if known): K052467 (corrected)

Device Name: Kyron™ Clinical Imaging, Inc. - BrainViewRx™ Viewer

INDICATIONS FOR USE:

BrainViewRx™ provides visualization of functional and physiologic brain imaging data. The software package provides both analysis and viewing capabilities that promote the integration of physiologic and functional imaging data sets, including blood oxygen level dependent (BOLD) fMRI, magnetic resonance spectroscopy (MRS), and MR diffusion including diffusion tensor imaging (DTI). The integration of these data, when interpreted by a trained physician, yields information that may assist in the diagnosis of brain pathology and the planning and monitoring of medical treatments.

Prescription Use ___X___ (Per 21 CFR 801 Subpart D) OR Over-the-Counter Use _____ (Per 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K052467